



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/EP98/04029</p> <p>(22) International Filing Date: 24 June 1998 (24.06.98)</p> <p>(30) Priority Data: 0749/97 25 June 1997 (25.06.97) DK</p> <p>(71) Applicant: BIOTAP APS [DK/DK]; Østre Havnevej 23-25, P.O. Box 80, DK-5700 Svenborg (DK).</p> <p>(72) Inventors: HESSEL, Lasse, Leif; Rantzausmindevej 111, DK-5700 Svenborg (DK). LUNDSGAARD, Jorgen, Scheming; Otto Rudsvej 1, DK-5700 Svenborg (DK). ZIMMERMANN-NIELSEN, Carl; Kogtvedparken 72, DK-5700 Svenborg (DK). ENGELL, John; Skattergade 3, DK-5700 Svenborg (DK). MALLING, Jesper; Langelinie 40, DK-5230 Odense M (DK). THOMAS, David, Morgan; Roerkaervej 1, DK-5771 Stenstrup (DK).</p> <p>(74) Agents: STEBBING, Peter, John, Hunter et al.; Ablett & Stebbing, 45 Lancaster Mews, Lancaster Gate, London W2 3QQ (GB).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>
<p>(54) Title: INTERCUTANEOUS IMPLANT DEVICE</p> <div data-bbox="315 1134 1234 1648"> </div> <p>(57) Abstract</p> <p>An intercutaneous implant device (1) useful in intraluminal and extraluminal procedures for externalisation of a vessel provided with a hollow cylinder (2) with an upper and lower end and interior and exterior surface, said hollow cylinder having a central aperture (10) which is greater in diameter than the intended exterior expanse of an access site and a length which is adapted to provide an adequate annular separation of the externalised vessel at the exterior and interior surface of the implant to ensure adequate blood supply to the vessel; a flange (3) extending from the upper end of the hollow cylinder which provides a platform onto which is attached a termination device; and a plane contacting surface (4) extending from the lower end of the hollow cylinder which provides a means for fixation of the implant to the patient.</p>		

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- 1 -

INTERCUTANEOUS IMPLANT DEVICE

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The present invention relates to bio-compatible polymeric implant devices for use as temporary or chronic intercutaneous conduit means for externalizing internal vessels and/or organs. The implant is constructed so as to provide a platform, onto
10 which can be mounted or attached a variety of detachable termination devices such as caps, removable pouches and tubes. The implant comprises a hollow cylinder or barrel terminated at its upper end by a flange and at the bottom end by a plane contacting surface. In a preferred embodiment, the implant
15 further comprises a plurality of textile fixtures or a textile ring extending perpendicularly from the plane contacting surface and/or hollow cylinder which can be fixed to the subcutis or muscle fascia to create a fibrous plate which fastens and stabilizes the implant thereby avoiding any tilting
20 of the implant during manipulation of any termination devices. Implants of the present invention are useful in both extraluminal and intraluminal procedures.

There are numerous medical conditions which require a
25 surgical procedure to externalize an internal body vessel such as, but not limited to, the colon, small intestine, ureter or bladder. For example, patients undergoing partial or total surgical removal of the colon generally require an enterostomy. Ileostomy is a surgical procedure wherein the small intestine
30 is opened and drained or brought through the abdominal wall.

- 2 -

Typically, enterostomies are accomplished by severing the vessel which is to be externalized and then suturing the wall of the vessel to an opening which has been formed on the surface of the body. The opening is normally located in the abdominal area. In time, the wall of the vessel and the dermis of skin surrounding the opening will grow together to permanently secure the vessel to the body surface. After the operation has healed, a container is typically attached to the surface of the skin to collect excrements which are discharged from the vessel. However, due to the acidic and enzymatic nature of fecal matter, ulcers often develop on the skin surrounding the point of externalization. Accordingly, various transcutaneous implant devices have been developed for use in enterostomies and other similar procedures which prevent matter being discharged from the externalized vessel or organ from contacting the skin.

For example, U.S. Patent 5,234,408 and U.S. Patent 5,290,251 disclose a tissue bondable cystostomy tube which overcomes problems with urinary leakage associated with suprapubic cystostomy and percutaneous cystostomy. This cystostomy tube comprises a subcutaneous hollow cylinder having an upper and lower end, a planar disc extending radially from the lower end of the subcutaneous hollow cylinder used for positioning and alignment of the subcutaneous hollow cylinder with the bladder membrane and a transcutaneous hollow cylinder also having a lower and upper end wherein the lower end of the transcutaneous hollow cylinder is slidably received into the upper end of the subcutaneous hollow cylinder. The exterior surface of both cylinders and the planar disc are coated with a material suitable for bonding with biological tissue. In a preferred embodiment, this cystostomy tube further comprises a stabilizing slipover disc sleeve centrally located on the exterior surface of the subcutaneous hollow cylinder which is also coated with a material suitable for bonding with biological tissue and which provides a means for stabilizing

- 3 -

and aligning the cystostomy tube in the patient. This cystostomy tube is surgically implanted in phases over a period of several weeks or months into the patient. The first phase involves implantation of the subcutaneous hollow cylinder with a removable plug in the region of the bladder membrane. The subcutaneous hollow cylinder and plug are allowed to remain in the patient for a sufficient period of time for tissue bonding to occur, i.e., several weeks or months. After this tissue bonding has occurred, a circular portion of skin and subcutaneous fat which forms above the subcutaneous hollow cylinder is excised. The plug is removed from the subcutaneous hollow cylinder and the lower end of the transcutaneous hollow cylinder is slidably inserted into the subcutaneous hollow cylinder. The two cylinders are then allowed to remain in the patient for a sufficient period of time for tissue bonding to occur to the transcutaneous hollow cylinder. The cystostomy tube is then activated by inserting a trocar into the transcutaneous hollow cylinder and puncturing the internal bladder membrane. A cap is then affixed to the upper end of the transcutaneous hollow cylinder.

U.S. Patent 4,183,357 discloses a chronic transcutaneous implant assembly for enterostomies. The implant device contains a cylindrical or barrel portion which is integrally linked to a flange portion. The barrel portion has a plurality of apertures or limited areas of porous material which enable the ingrowth of the tissue of the externalized vessel through the implant into the dermis thereby forming a vascularized connection for the vessel and preventing necrosis. The flange portion also has a plurality of apertures or limited areas of porous material which enable the ingrowth of vascularized dermis tissue to form a biological anchor for the implant. It is preferred that the implant device be combined with a disposable, detachable bag member which functions to receive excrements exiting the externalized vessel.

- 4 -

U.S. Patent 4,534,761 (Raible et al.) also discloses an implant device which includes a passageway extending through the device and an anchor means which preferably includes a plurality of apertures for establishing a biological anchor.

5 In one embodiment, the implant device also includes an annular rim which forms an annular recess between the annular rim and the anchor means. Grafting mesh is also positioned annularly about at least a portion of the exterior of the implant device. The grafting mesh is spaced apart from the implant device by

10 means of a spacer in order to allow tissue ingrowth between the implant device and the grafting mesh.

However, experience in these surgeries indicates that interference with the blood supply to the externalized vessel leads to complications, particularly loss of viability. This

15 necessitates reformation of the enterostomy with viable vessel. Direct mucocutaneous contact with the implant, which occurs in the implant devices described above, reduces the blood supply to the adjacent tissue via the mesentery thereby causing necrosis. It is also difficult to maintain the biocompatible

20 bond to the implant, due to excessive local stress at the interface between tissue and implant.

Another problem arises due to the passage of intestinal content through the implant aperture where peristaltic activity is absent, e.g., pathogenesis during Hirschprung's type

25 syndrome. When passage of intestinal fluids occurs due to increase of the intraluminal pressure in the colon, then problems requiring irrigation can arise.

In the present invention, an improved implant for the general purpose of externalizing vessels is provided which

30 overcomes these disadvantages.

An object of the present invention is to provide an intercutaneous implant device useful in intraluminal and extraluminal procedures for externalization of vessels which

- 5 -

comprises a hollow cylinder having an upper and lower end and an interior and exterior surface, said hollow cylinder having a central aperture which is greater in diameter than the exterior expanse of the access site and a length which provides
5 for adequate annular separation of the externalized vessel at the exterior and interior surface of the implant to ensure adequate blood supply to the vessel; a flange extending from the upper end of the hollow cylinder which provides a platform onto which is attached a termination device; and a plane
10 contacting surface extending from the lower end of the hollow cylinder which provides a means for fixation of the implant to the patient. In a preferred embodiment, the implant further comprises a textile ring or fixtures extending perpendicularly from the plane contacting surface and/or hollow cylinder of the
15 implant which can be sutured into the muscle for added support.

The invention will now be described, by way of illustration only, with reference to the following examples and the accompanying figures.

Figure 1 shows a cross-sectional side view of an implant of the present invention.

Figure 2A shows a top view of a preferred embodiment of an implant of the present invention which depicts a textile ring extending perpendicularly from the hollow cylinder of the implant.

Figure 2B shows a top view of a preferred embodiment of an implant which depicts textile fixtures extending perpendicularly from the hollow cylinder of the implant.

Figure 3A shows a cross-sectional side view of the implant *in situ* in an extraluminal procedure wherein the cutis is designated by A; the subcutis is designated by B; the fascia and muscle are designated by C; the peritoneum is designated by D; and the colon with supplying vascularization is designated by E.

Figure 3B show the external view of the implant in this extraluminal procedure.

- 6 -

Figure 4A shows a cross-sectional side view of the implant in situ in an intraluminal procedure wherein the cutis is designated by A; the subcutis is designated by B; the fascia and muscle are designated by C; the peritoneum is designated by D; and the colon with supplying vascularization is designated by E. The intraluminal procedure involves introduction of the implant device through the abdominal wall and into the intestinal lumen, such as the colon sigmoideum.

Figure 4B shows the external view of the implant in this intraluminal procedure.

Figure 5 shows a side view of an embodiment of an implant wherein the hollow cylinder is formed as a helical screw and the plane contacting surface is formed by a plurality of cutting edges which terminate as concurrent threads of the helical screw to enable penetration of the cutaneous tissue on axial rotation of the implant.

Examples

In the present invention a biocompatible polymeric implant is provided for use in externalizing vessels. It is intended to be applied in connection with access to body tissue and access or externalization of internal vessels, such as intestines, bladder, etc., or any other amenable organ in the body. The implant is constructed so as to provide a platform onto which can be mounted or attached a variety of detachable termination devices, such as caps, removal bags, tubes, etc. During application, the implant penetrates through the epithelium, dermis and subcutaneous adipose tissue to rest on the deep fascia below, to which it may be secured by suture. When used in enterostomy or colostomy, the implant device of the present invention allows protection of the abdominal skin from the adverse effects of contact with excrement, and also avoids the use of adhesives in order to attach disposable, detachable collection bags directly onto the skin.

- 7 -

In simplest form, as depicted in Figure 1, the implant 1 comprises a hollow cylinder 2 terminated at its upper end by a flange 3 and at the bottom end by a plane contacting surface 4. The flange 3 of the implant 1 provides a platform, onto which can be mounted or attached a variety of detachable termination devices such as caps, removable pouches and tubes while the plane contacting surface 4 provides a means 5 for fixation of the implant to the patient. For example, in one embodiment, the plane contacting surface 4 is perforated to facilitate suturing of the implant to the muscle fascia.

The implant material is selected from the list of biocompatible materials approved by the U.S. Food and Drug Administration (FDA). The preferred material is a moldable polyester thermoplastic which has been found on the list of approved materials.

In one embodiment, to be used for implanting in the usual manner where established conventional surgical procedures apply, the hollow cylinder 2 of the implant 1 has a non-profiled portion which is covered with a textile surface layer 5 comprised of a porous polymer such as, but not limited to, DACRON mesh, PROLENE net, VICRYL net, or SURGIPRO mesh, for integration of the implant 1 between the external skin tissue and the internal vessel and/or organ. This covering provides for rapid vascularization and tissue ingrowth around the implant thereby assuring stability.

It is also very important to maintain blood supply to the tissues in contact with the implant. Accordingly, in the present invention, the implant 1 is removed from the access site by having a central aperture to its hollow cylinder 2 which is considerably greater than the exterior expanse of the access site. Further, subsequent surgeries may require access to the vessel which may be manipulated via the open aperture in the hollow cylinder of the implant. Accordingly, the size of the central aperture must be adequate to enable the

- 8 -

manipulations required and is determined by the diameter of the enclosed stoma. For example, for colostomies, the diameter of the central aperture is the expected diameter of the outer skin surface of the externalized vessel and ranges from
5 approximately 15 mm to 55 mm. However, as will be obvious to those of skill in the art upon this disclosure, the size of the central aperture of the hollow cylinder range is selected to provide for adequate control of interference and compatibility and is dependent upon the vessel being accessed.

10 The extent of the annulus separating the externalized organ boundary at the exterior and the internal surface of the implant must be sufficient to ensure adequate blood supply to the vessel. Typically, an annular separation of 5 to 25 mm from the externalized vessel is required. However, this may
15 vary in accordance with the amount and/or thickness of adipose tissue of the patient. Adipose tissue thickness normally varies between 5 and 40 mm. Thus, the length of the hollow cylinder of the implant must be adjusted accordingly to provide for adequate annular separation of 5 to 25 mm.

20 For example, in enterostomy or colostomy there must be adequate space for a portion of the mesentery or mesocolon to be carried up to the surface; otherwise, the externalized vessel will be likely to lose viability. The use of an implant in this way serves to provide a remote support to the accessed
25 organ with a minimum of interaction with its function. The function of the implant is, therefore, to act as a support and at the same time, offer a platform for mounting various accessories, such as detachable bags, tubes, instrumentation, terminators and the like. Thus, in a preferred embodiment as
30 depicted in Figure 2A and 2B, the implant 1 further comprises a plurality of textile fixtures or fingers 6 (depicted in Figure 2B) or a textile ring 7 (depicted in Figure 2A) extending perpendicularly from the plane contacting surface of the implant which can be sutured into the muscle for added support.
35 More preferably, the implant further comprises a plurality of

- 9 -

textile rings or fingers 6 extending from the hollow cylinder 2 of the implant 1. It is preferred that the textile rings or fingers comprise of a porous polymer such as, but not limited to, DACRON, PROLENE net, VICRYL net, or SURGIPRO mesh.

5 In this embodiment, the implant 1 is fixed to the subcutis or muscle fascia to create a fibrous plate which fastens and stabilises the implant thereby preventing tilting of the implant 1 upon manipulation of the detachable termination device at the flange 3. By using this embodiment, and in
10 particular the implant 1 wherein textile fixtures or fingers 6 or multiple layers thereof extend from the plane contacting surface 4, optimal supply of blood to the tissue involved is maintained and vitality is improved for the normal tissue surrounding the stoma aperture.

15 Accordingly, the present invention provides a useful implant for permanent access to a vessel or organ such as may be required, for example, in a permanent colostomy, sigmoidostomy or transverse colostomy. Permanent colostomy (sigmoidostomy) using the implant of the present invention
20 requires prior establishment of a relieving transverse stoma until the implant has been integrated and the associated wound healed. Further, to prevent Hirschprung's type syndrome at the constricting exit, especially for sigmoidostomy, the hollow cylinder 2 of the implant 1 is designed to convey peristalsis
25 into the constriction formed by the implant. Hirschprung's type syndrome arises due to a loss of peristalsis in the bowel. Hirschprung's disease is actually caused by an absence of nerve cells in the wall of the bowel. Collections of nerve cells, called ganglia, control the coordinated relaxation of
30 the bowel wall that is necessary for bowel contents to advance. Thus, in Hirschprung's disease, the portion of the bowel without ganglia cannot relax and thus remains collapsed so that stools cannot pass. A similar phenomena occurs with traditional implants which are not capable of peristalsis.

- 10 -

However, material flow due to peristalsis can be assisted by appropriate design. When the flow length of an implant is large, considerable resistance to flow can arise which is similar conceptually to Hirschprung's type syndrome. The rise
5 in abdominal pressure needed to overcome the flow resistance indicates that at least for extraluminal uses as depicted in Figure 3A and 3B, a flexible pipe capable of responding to peristaltic waves is more amenable. Thus, in one embodiment of the present invention, the inner surface of the hollow
10 cylinder 2 is smooth but the wall is flexible and capable of changing diameter significantly upon extension and distention of the cecum. In this embodiment, it is preferred that the hollow cylinder comprises an elastomeric tube with double spiral cord reinforcements.

15 In extraluminal procedures such as permanent colostomy prior establishment of a relieving transverse stoma until the implant has been integrated and the associated wound healed is required. In this procedure, the closed proximal sigmoideum is drawn through the abdominal incision and a normal colostomy
20 operation is performed and concluded. Subsequently, after healing, a circular incision is made around the stoma down to the muscle fascia. The implant is then introduced around the stoma, and the plane contacting surface of the implant is sutured to the fascia. The upper flange is sutured to the
25 dermis and, where used, the fingers of the textile material or textile ring are secured to the surrounding tissues.

Implants of the present invention are also useful in intraluminal procedures as depicted in Figure 4A and 4B. When carrying out intraluminal procedures, it is preferred that the
30 implant be rigid to avoid collapse due to abdominal pressure. In intraluminal procedures, a side opening in the tenia is made on the terminated proximal sigmoideum and a hole is prepared with purse string sutures. The implant is introduced via the colostomy aperture in the abdominal wall and fitted into the
35 prepared aperture in the sigmoideum. The purse string suture

- 11 -

is secured and the sigmoideum wall is brought into contact and attached to the parietal peritoneum surrounding the exterior surface of the implant. The flange at the upper end of the hollow cylinder of the implant is sutured to the surrounding
5 dermis.

Another object of the implant of the present invention is facilitation of implantation. Removal of possible interaction offers an opportunity for specializing on the support function described above, without unnecessarily
10 complicating the operation. This means that access and implantation can be part of a two stage process in which each stage can be carried out in a sequential manner as separate, distinct steps.

The step of implantation can then be simplified, facilitated
15 and made more reliable. In an embodiment of Figure 5 which exploits these possibilities, a simple implantation may be carried out by using a simple self-incising screw technique. The hollow cylinder 2 may be formed with a helical screw 8. In this embodiment, as depicted in Figure 5, the plane contacting
20 surface is formed by a plurality of cutting edges 9 which terminate as concurrent threads of the helical screw. The purpose of the cutting edges 9 is to enable penetration of the cutaneous tissue on axial rotation of the implant. In this embodiment, it is preferred that the upper portion of the
25 hollow cylinder 2 including the flange 3 be covered with a porous material, for example, DACRON velour, which enables and encourages tissue ingrowth.

The implant may conveniently be introduced prior to or following access surgery, by applying vertical pressure on the
30 top surface of the hollow cylinder 2, while rotating the hollow cylinder 2 to the angle required to give the calculated penetration depth. The appliance may be utilized in post-operative retro-fitting, where complications arising from the use of conventional termination devices require alternative

- 12 -

measures which address the disadvantages. The screw pitch may be varied in order to give optimal penetration efficiency at a reasonable torque so that fitting the implant does little damage to the tissue in the surrounding area.

5

- 13 -

Claims

1. An implant device (1) comprising:
 - a) a hollow cylinder (2) having an upper and lower end
5 and an interior and exterior surface, said hollow cylinder having a central aperture (10) which is greater in diameter than the exterior expanse of an access site and a length which provides for adequate annular separation of an externalized vessel at the exterior and interior surface of the implant,
 - 10 b) a flange (3) extending from the upper end of the hollow cylinder which flange provides a platform onto which is attached a termination device; and
 - c) a plane contacting surface (4) extending from the lower end of the hollow cylinder which provides a means for
15 fixation of the implant.
2. An implant device of claim 1 wherein the exterior surface of the hollow cylinder comprises a textile surface layer (6,7) comprised of a porous polymer.
20
3. An implant device of claim 1 or claim 2 further comprising a textile ring (7) or a plurality of textile fixtures (6) extending perpendicularly from the plane contacting surface of the implant.
25
4. An implant device of claim 3 further comprising a plurality of textile rings (6) extending perpendicularly from the hollow cylinder of the implant.
- 30 5. An implant device of any preceding claim wherein the hollow cylinder is rigid.
6. An implant device of any of claims 1 to 4 wherein the hollow cylinder is flexible and capable of changing diameter
35 upon extension and/or distension of the vessel.

- 14 -

7. An implant device of claim 6 wherein the hollow cylinder is formed of an elastomeric material with spiral wound reinforcement.
- 5 8. An implant device of any preceding claim wherein the hollow cylinder is formed with a helical screw (8) and the plane contacting surface is formed by a plurality of cutting edges (9) which terminate as concurrent threads of said helical screw.

1/5

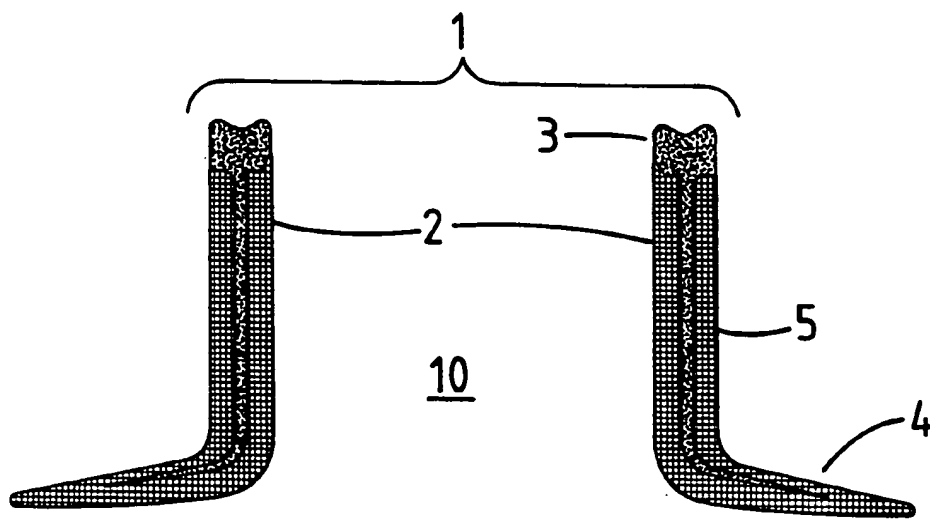


FIG. 1

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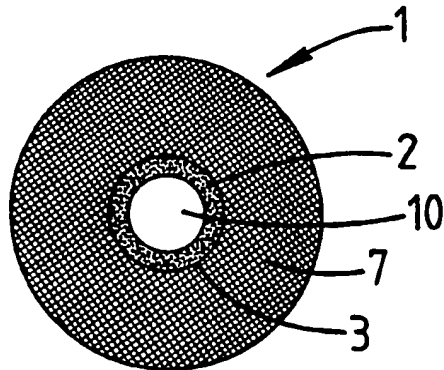


FIG. 2A

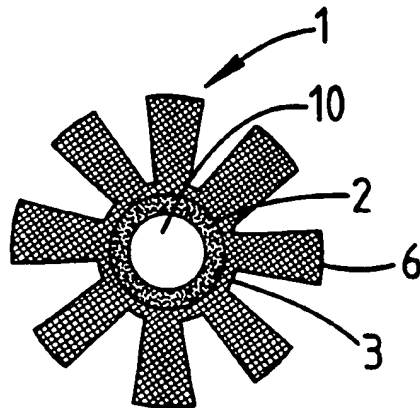


FIG. 2B

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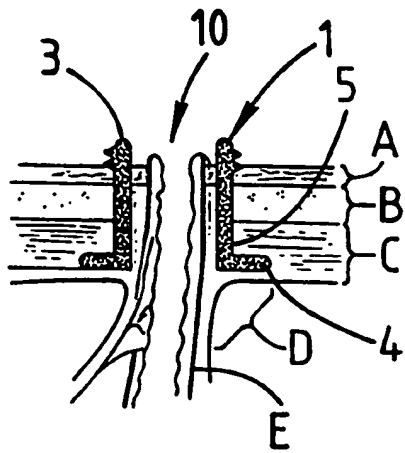


FIG. 3A

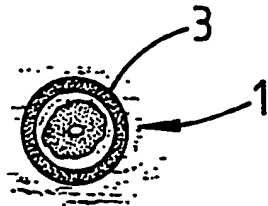


FIG. 3B

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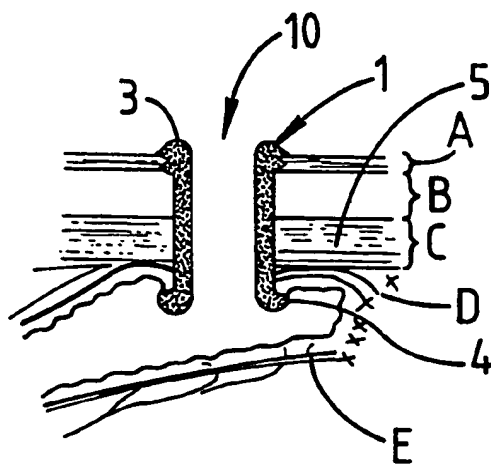


FIG. 4A

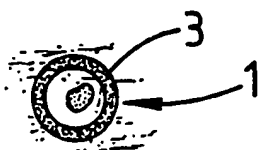


FIG. 4B

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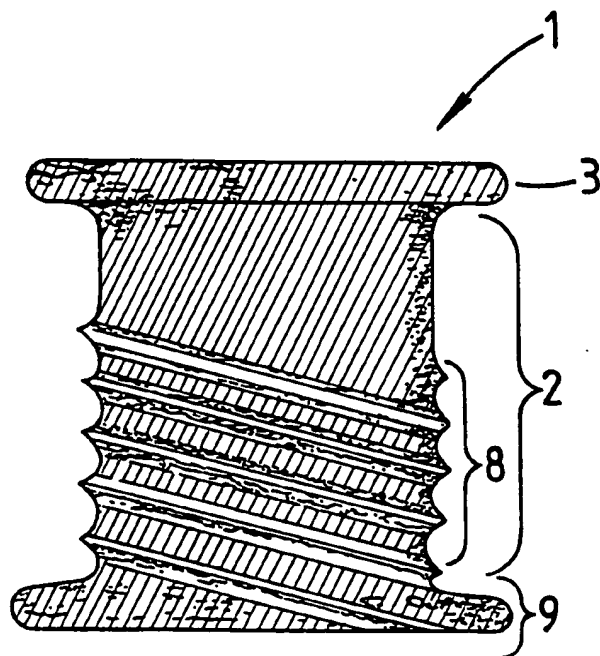


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 98/04029

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/00 A61F5/445

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 056 282 A (BENTLEY LAB) 18 March 1981 see page 2, line 76 - page 2, line 122; figures 1-15	1-5
X	US 4 183 357 A (BENSON JAMES A ET AL) 15 January 1980 cited in the application see column 3, line 52 - column 4, line 16; figures 1-5	1,5
A	US 3 216 420 A (D.E. SMITH & B.D. CLAYCOMB) 9 November 1965 see column 2, line 52 - column 4, line 6; figures 1,2,9	1-5
A	US 4 265 244 A (HILL ROGER C) 5 May 1981 see the whole document	1-5

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Donnelly, C

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	<p>EP 0 592 131 A (GRAY MICHAEL WILLIAM) 13 April 1994 see column 7, line 45 - column 8, line 58; figures 2,5</p> <p>-----</p>	1-4,6,7

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